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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/706,088	11/13/2003	Denise L. Doolan	NC 84,381	8196

22245 7590 12/14/2009

NAVAL MEDICAL RESEARCH CENTER
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EXAMINER	
ZEMAN, ROBERT A	
ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
12/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/706,088	DOOLAN ET AL.	
	Examiner	Art Unit	
	ROBERT A. ZEMAN	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6 and 8-26* is/are pending in the application.

4a) Of the above claim(s) *18-26* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6 and 8-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9-30-2009 has been entered.

The amendment filed on 9-30-2009 is acknowledged. Claims 1, 3, 6, 8 and 17 have been amended. Claims 5 and 7 have been canceled. Claims 1-4, 6 and 8-26 are pending. Claims 18-26 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-4, 6 and 8-17 are currently under examination.

Claim Rejections Maintained

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 1-4, 6 and 8-17 under 35 U.S.C. 103(a) as being unpatentable over McMichael et al. (WO 98/56919 – IDS filed on 4-11-2008) and Sallberg et al. (U.S. Patent Application Publication US 2002/0165172) is maintained for reasons of record.

Applicant argues:

1. McMichael et al. fails to teach the use of alphavirus generally or the use of VEE specifically or the specific malarial antigens of the instant claims.

2. Sallberg et al. fail to teach the specific use of VEE or any malarial antigen except PfSCP.

3. The combination of references does not teach the specific malarial antigens recited in the amended claims.

4. Since the recited antigens are critical components of the immunization preparation and are responsible for the preparation's immunogenicity against malaria, an immunization method without clearly defined antigens cannot anticipate the current invention.

Applicant's arguments have been fully considered and deemed non-persuasive.

With regard to the specific disclosure of the use of VEE, given that Sallberg et al. disclose the use of the entire class of alphaviruses, the use of VEE is deemed to be an obvious variation of the disclosed vectors. Moreover, given said alphavirus vectors are well known in the

art yielding predictable results, it is obvious for the skilled artisan to use the VEE. (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007]). Moreover, since the recited malarial antigens are well known in the art yielding predictable results, their use is obvious for the skilled artisan (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007])

With regard to Point 4, the rejection was made under 35 U.S.C. 103(a), hence the basis of the rejection is obviousness, not anticipation.

Finally, it should be noted that only claim 3, recites the specific use of VEE.

As outlined previously, McMichael et al. disclose methods of inducing a CD8 T cell immune response to malarial antigens comprising the administration of a priming composition and a boosting composition wherein said boosting composition comprises a non-replicating or replication impaired pox virus vector (see abstract). Moreover, McMichael et al. further disclose the priming composition can comprise a nucleic acid (either DNA or RNA) that is packaged or in free form (see page 11, lines 4-8), Ty-VLP or a recombinant adenovirus (see page 12, lines 4-5). McMichael et al. further disclose that the MVA can be used (see page 12, lines 6-9) in both the priming and boosting compositions (see page 13, line 29-30) and that a variety of viral vectors (including herpes virus) can be used in the priming composition (see page 13, lines 7-16).

McMichael et al. differs from the instant invention in that they do not explicitly disclose the use of priming compositions comprising alphaviruses, generally or Venezuelan Equine Encephalitis Virus specifically. Moreover, McMichael et al. do not explicitly disclose the use of PfEXP1, PfSSP2, PfSSP2, PfLSA-3, PfMSP-1, PfAMA-1, PfEBA-175, PfMSP-3, PfMSP-4, PfMSP-5, PfRAP-1, or PfRAP-2 as the antigens encoded by said Alphaviruses.

Sallberg et al. disclose the use of Alphaviruses in methods for treating or preventing malaria (see paragraph [0050]).

Consequently it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the alphaviruses disclosed by Sallberg et al. in the compositions and methods disclosed by McMichael et al. in order to take advantage of the ability of the Alphaviruses to treat intracellular infections.

Moreover, since the recited malarial antigens are well known in the art yielding predictable results, their use is obvious for the skilled artisan (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007])

One would have had a reasonable expectation of success as alphaviruses have been successfully used in other vaccine compositions and methodologies (see Sallberg et al. al.).

New Grounds of Rejection

35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Said claim is rendered vague and indefinite by the use of improper Markush language (see lines 8-13 of the claim).

35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6 and 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMichael et al. (WO 98/56919 – IDS filed on 4-11-2008), Sallberg et al. (U.S. Patent Application Publication US 2002/0165172) and Paoletti et al. (U.S. Patent 5,766,597).

McMichael et al. disclose methods of inducing a CD8 T cell immune response to malarial antigens comprising the administration of a priming composition and a boosting composition wherein said boosting composition comprises a non-replicating or replication impaired pox virus vector (see abstract). Moreover, McMichael et al. further disclose the priming composition can comprise a nucleic acid (either DNA or RNA) that is packaged or in free form (see page 11, lines 4-8), Ty-VLP or a recombinant adenovirus (see page 12, lines 4-5). McMichael et al. further

disclose that the MVA can be used (see page 12, lines 6-9) in both the priming and boosting compositions (see page 13, line 29-30) and that a variety of viral vectors (including herpes virus) can be used in the priming composition (see page 13, lines 7-16).

McMichael et al. differs from the instant invention in that they do not explicitly disclose the use of priming compositions comprising alphaviruses, generally or Venezuelan Equine Encephalitis Virus specifically. Moreover, McMichael et al. do not explicitly disclose the use of PfEXP1, PfSSP2, PfSSP2, PfLSA-3, PfMSP-1, PfAMA-1, PfEBA-175, PfMSP-3, PfMSP-4, PfMSP-5, PfRAP-1, or PfRAP-2 as the antigens encoded by said Alphaviruses.

Sallberg et al. disclose the use of Alphaviruses in methods for treating or preventing malaria (see paragraph [0050]).

Paoletti et al. disclose the use of recombinant poxvirus expressing *Plasmodium* antigens including PfSSP2, PfLSA-1 and PfAMA-1 as a vaccine against *Plasmodium* species (see abstract).

Consequently it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the alphaviruses disclosed by Sallberg et al. and the poxviruses of Paoletti et al. in the compositions and methods disclosed by McMichael et al. in order to take advantage of the ability of said viruses to treat intracellular infections.

Moreover, since the recited malarial antigens are well known in the art yielding predictable results, their use is obvious for the skilled artisan (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007])

One would have had a reasonable expectation of success as alphaviruses and poxviruses have been successfully used in other vaccine compositions and methodologies (see Sallberg et al.

al. and Paoletti et al.).

Claims 1-4, 6 and 8-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMichael et al. (WO 98/56919 – IDS filed on 4-11-2008), Sallberg et al. (U.S. Patent Application Publication US 2002/0165172) and Paoletti et al. (WO 94/28930).

McMichael et al. disclose methods of inducing a CD8 T cell immune response to malarial antigens comprising the administration of a priming composition and a boosting composition wherein said boosting composition comprises a non-replicating or replication impaired pox virus vector (see abstract). Moreover, McMichael et al. further disclose the priming composition can comprise a nucleic acid (either DNA or RNA) that is packaged or in free form (see page 11, lines 4-8), Ty-VLP or a recombinant adenovirus (see page 12, lines 4-5). McMichael et al. further disclose that the MVA can be used (see page 12, lines 6-9) in both the priming and boosting compositions (see page 13, line 29-30) and that a variety of viral vectors (including herpes virus) can be used in the priming composition (see page 13, lines 7-16).

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Sallberg et al. disclose the use of Alphaviruses in methods for treating or preventing malaria (see paragraph [0050]).

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including PfSSP2, PfLSA-1 and PfAMA-1 as a vaccine against *Plasmodium* species (see abstract).

Consequently it would have been obvious for one of ordinary skill in the art at the time the invention was made to use the alphaviruses disclosed by Sallberg et al. and the poxviruses of Paoletti et al. in the compositions and methods disclosed by McMichael et al. in order to take advantage of the ability of said viruses to treat intracellular infections.

Moreover, since the recited malarial antigens are well known in the art yielding predictable results, their use is obvious for the skilled artisan (see *KSR International Co. v. Teleflex Inc.*, No. 04-1350 [U.S. Apr. 30, 2007])

One would have had a reasonable expectation of success as alphaviruses and poxviruses have been successfully used in other vaccine compositions and methodologies (see Sallberg et al. al. and Paoletti et al.).

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ROBERT A. ZEMAN whose telephone number is (571)272-0866. The examiner can normally be reached on Monday- Thursday, 7am -5:30 p.m. .

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov.

Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Robert A. Zeman/
Primary Examiner, Art Unit 1645
December 9, 2009